APPRENTICE

Where Is Pharma Headed in 2023?

Learn 10 disruptive trends that are shaping the future of life science manufacturing.

Find out how to adapt so you can stay on target and ahead of the curve.

Table of Contents

Executive Summary

The pharmaceutical industry is ripe with growth, registering a compound annual growth rate (CAGR) of 9.1% from 2021 to 2022. Although revenues are on the rise, reaching $1.42 trillion in 2021, various challenges currently plague the industry. From historically high inflation to supply chain issues, the looming economic crisis, and shifting consumer preferences, it's more important now than ever for life science organizations to adapt.

This eBook provides an overview of 10 disruptive trends impacting the pharmaceutical industry in 2023. In preparing the trends outlined in the pages that follow, we interviewed subject matter experts and conducted independent research to get a better understanding of where the industry is heading.

We begin with a snapshot review of 2022, and then dive into each trend, starting with cell and gene therapies and concluding with blockchain technology. Powered by the insights in this book, life science professionals can stay ahead of the curve and prepare for a successful 2023 and beyond.

2022: A Snapshot

2022 was a busy year for the pharma industry. The market grew exponentially, reaching a CAGR of 9.1%. Novel therapeutics to treat chronic illnesses and life-threatening diseases such as diabetes, recurrent ovarian cancer, amyotrophic lateral sclerosis (ALS) hit the market. On average, the Food and Drug Administration (FDA) granted approvals to 2.5 net-new pharma products per month.

At the time of writing this report (in December of 2022), the 2022 totals are still a work in progress. However, based on current market trends, we anticipate that the total number will fall just below 2021's total approval number of 50. This makes sense, given it takes 10 to 12 years, on average, to commercialize a new therapeutic product.

In addition, the industry is still reeling from the impact of COVID-19. Unable to travel from site to site, or even work in person depending on the role, pharma companies started implementing cutting-edge tech solutions to maintain, and expedite, **pharmaceutical manufacturing**. This shift was evident in 2020, and continues to this day.

Recognizing the market uncertainties, pharma companies are becoming increasingly tech-savvy in an effort to stay ahead of the curve.

As with anything creating mass movement, early adoption is key. The industry has already shifted in R&D, and won't be going back to its previous discovery and development model in a world without High Throughput Screening (HTS) and robotics.

The same shift is now happening throughout the drug manufacturing lifecycle, from preclinical through clinical all the way to commercial.

On the following pages, we'll walk you through 10 trends to keep an eye on in 2023.

TREND #1

Cell & Gene Therapies on The Rise

Although our DNA is **99.9% identical** from person to person, the 0.1% disparity makes a huge difference when it comes to treating various diseases and conditions.

Life science professionals are realizing how important it is to treat the person, rather than the illness — which is why cell and gene therapies (CGT) are on the rise.

This approach to therapeutics involves extracting DNA such as cells, protein, or other genetic material from a patient or donor and then altering the DNA to provide patients with personalized medicine. CGT may also have a longer-lasting impact compared to traditional medicinal approaches.

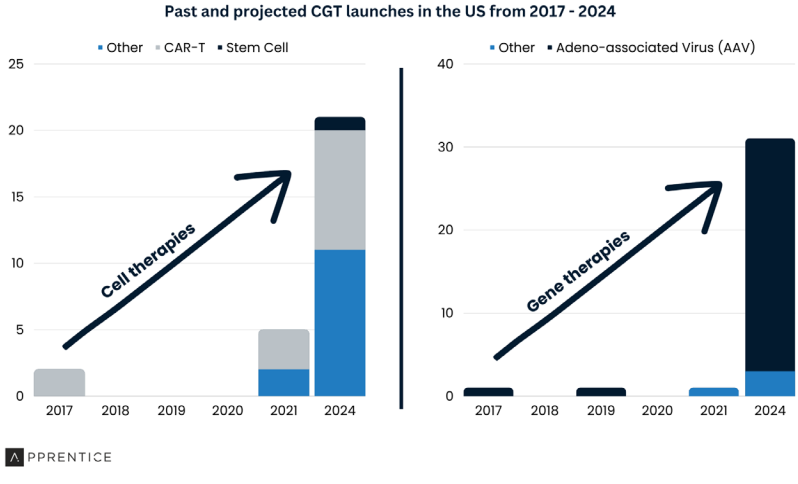

Figure 1: Number of past and projected US-based CGT launches from 2017 - 2024 [Source: McKinsey]

While beneficial, CGT today is expensive and time consuming. For autologous therapies, every treatment is custom-made for

an individual, which requires a more complex and smaller batch manufacturing process than traditional small molecule drugs.

> *"Despite the fact that cell and gene therapeutics are on the rise, organizations need to find a way to reduce costs and increase the speed of manufacturing in order to achieve short- and long-term success."*
>
> — Keith Bowen, MES/LES Advocate, Apprentice

Even still, biologics (biosimilars) sales are growing two times as fast as non-biologics for the top 20 pharma companies. In addition, estimates predict that annual sales growth will be around 15% for cell therapies and 30% for gene therapies.

In 2023 and beyond, we expect to see a massive uptick in CGT's being researched and developed, as well as new companies emerging on the scene.

To commercially scale CGT therapies, we anticipate a large rise in allogeneic therapies, where a single source donor can be used to treat multiple patients.

Estimates predict that annual sales growth for cell therapies will be 15% and 30% for gene therapies. [Source: C&EN]

TREND #2

Reliance on Big Data & Analytics

When the COVID pandemic spread like wildfire across the globe, it put massive pressure on pharma organizations to develop a vaccine — as fast as humanly possible. It was truly a life-or-death situation, and life science professionals rose to the occasion. But without big data and analytics, the outcome would have been very different.

Big data collates vast amounts of complex data sets and insights relating to biosimilars, disease status, personality traits, genetic information, and so forth. These details paint a comprehensive picture for researchers, allowing them to achieve in a matter of weeks or months what used to take years.

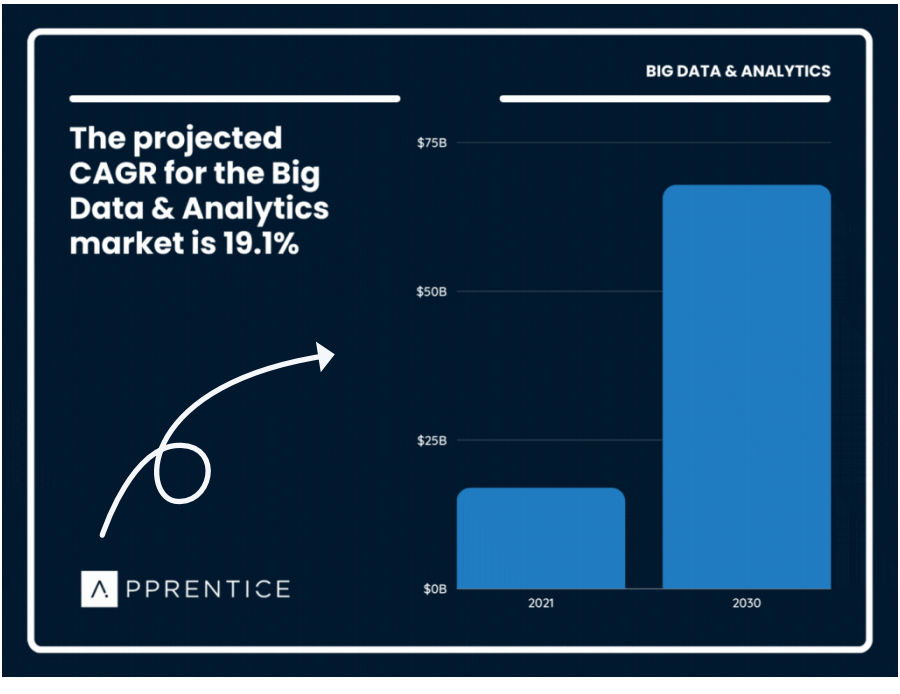

Figure 2: Projected CAGR of 19.1% for global big data in healthcare from 2022 to 2030 [Source: Spherical Insights]

In 2021, big data exceeded $16.87 billion in the global market and shows no sign of slowing down, with an expected growth rate of 19.1% by 2030.

Big data and analytics are especially critical when it comes to determining the best clinical trial participants, the results of which determine whether the drug will move on to the next stage or be granted Food and Drug Administration (FDA) approval.

In conjunction, big data and analytics also enable pharma companies to have critical process parameters (CPPS) and Critical Quality Attributes (CQAs) in near real-time.

This allows them to monitor variables and control drug production to ensure quality standards are met. It also accelerates the drug discovery and development process as a whole.

Big data and analytics in the healthcare sector was valued at $16.87 billion in 2021, and it's projected to reach $67.82 billion by 2030 — representing a whopping CAGR of 19.1%. [Source: GlobeNewswire)

TREND #3

Transition From Paper to Digital

Although paper is widely available and easy to source, it isn't easy to sift through or maintain. It can take weeks or months to organize and review procedures and batches for regulatory compliance. Plus, it's expensive and is likely to rise in price with the focus on sustainability for most businesses.

Time spent processing paper documents costs companies $19.7k per worker, per year. For big pharma companies, this can easily amount to hundreds of thousands of dollars — or more — annually.

In addition to the high cost and general inconvenience, paper is also prone to human error. This means issues related to tech transfers, batch production, and other processes may arise down the line.

To reduce costs and increase efficiency, pharma companies are transitioning from paper to digital solutions. This provides them with access to real-time data, which reduces the likelihood of deviations and speeds up time to market.

> *"The problem with pharma is… pharma. Industry professionals get caught up in the nitty gritty adherence, over-documentation, paralysis analysis, and so forth. They go to the nth degree on some of these rulings and lose sight of the broad principles that the FDA is trying to achieve.*
>
> *In essence, they lose the forest for the trees. Going paperless is a way to get back to the forest."*
>
> — Keith Bowen, MES/LES Advocate, Apprentice

Time spent processing paper documents costs companies $19.7k per worker, per year. [Source: IDC]

TREND #4

Accelerated Cloud Adoption

Sixteen out of the top 20 pharma companies leverage cloud technology to accelerate drug production. And in 2022, **57% of businesses** moved operations to cloud-based software solutions.

But what's the reason behind this mass cloud migration? In short, the need to increase speed and heighten security, while decreasing costs.

Pharma cloud-based platform solutions are designed to maintain stringent compliance, security, and privacy standards. Nowadays, many cloud providers abide by security and compliance standards such as GDPR, ISO 26001, cHXO, and 21 CFR Part 11.

This enables companies to protect their sensitive data and processes, both of which are paramount in the highly regulated pharmaceutical industry.

In fact, the cloud can help to facilitate FDA compliance. Because cloud providers update their software on an ongoing basis, they're able to stay up to date on evolving regulatory requirements and Good Manufacturing Practices (GMP).

Best of all, cloud software provides the means for instantaneous communication — the missing piece of the puzzle for true cross-functional collaboration.

By adopting cloud technology, pharmaceutical organizations can harness the power of real-time data visibility to keep everyone on the same page and share crucial information when it's needed most. Which means staying on track, under budget, and ahead of the curve.

Organizations that don't make the switch are likely to get left behind as technology continues to advance.

16 out of the top 20 pharma companies leverage cloud technology. [Source: McKinsey]

TREND #5

New Approach to Validation

In September of 2022, the FDA released draft Computer Software Assurance (CSA) guidance for pharmaceutical manufacturers.

This guidance is intended to both define the new CSA approach, and to elucidate the testing methodologies that will be needed to fulfill it.

The industry shift from Computer Systems Validation (CSV) to CSA will trigger a number of changes in the pharmaceutical industry. Chief among them is the increasing emphasis on critical thinking as a validation tool.

To adhere to the existing CSV methodology, manufacturers need to spend around 80% of their time creating documentation, and only 20% of their time on the actual testing.

With CSA, the FDA wants manufacturers to shift this approach so that they can spend the bulk of their time and efforts on testing and critical thinking.

While critical thinking will be the new focus of the CSA approach, testing certainly isn't getting lost by the wayside.

As Ken Shitamoto, Head of IT Quality Engineering at Gilead explains, "CSA does not reduce testing; CSA advocates more testing with less documentation. It is more important to remove defects than to collect documentation for inspection."

Some forward-thinking organizations have already made the shift, while others will follow in early to mid 2023.

Our two cents: change your approach to validation sooner, rather than later. It's much better to be ahead of the curve so you have time to work out any issues in advance, train your staff, and update your processes.

With the CSA methodology, the FDA expects manufacturers to spend 80% of their time on testing, and 20% on documentation. [Source: Kalleid]

TREND #6

More Integrated Supply Chains

Supply chains make the pharma world go round. In order to keep the production wheel in motion, proactive planning is key.

To achieve this, pharma companies are connecting their internal and external manufacturing stakeholders in a cloud environment. This provides all parties with access to real-time insights related to supply, demand, inventory management, and raw materials.

Equipped with this information, organizations can pivot quickly, make informed pharmaceutical manufacturing decisions, and work from the same dataset — regardless of location.

Plus, it offers greater collaboration between pharma companies and their Contract Development and Manufacturing Organizations (CMOs/CDMOs). In turn, this allows these organizations to plan better and avoid disruptions because data is continuously flowing in and out between the two stakeholders.

In addition, an integrated supply chain also allows for greater quality control, as products can be traced throughout the supply chain, including when in transit and on shelves.

This provides companies with great control over the quality and integrity of their products, as they can ensure therapeutics are handled and stored appropriately.

Although the initial integration process may sound like a heavy lift for many organizations, the use of platform solutions reduces the pain to benefit from the gain.

In 2023, we expect to see more pharma companies adopting this approach to streamline production and accelerate time to market.

Pharma companies are expected to lose an average of 24% of one year's earnings before interest, taxes, depreciation, and amortization every 10 years, due to supply chain disruptions. [Source: McKinsey]

TREND #7

CDMOs to Play a Bigger Role

Seventy-five percent of the biologics pipeline comes from small- and-medium-sized companies, and 60% of these organizations use CDMOs.

Our point? In 2023, and onward, CDMOs are going to play a much bigger and more influential role in drug production.

> *"CDMOs are a crucial piece in the pharmaceutical industry that helps bring treatments to patients faster. They provide manufacturing capacity and development expertise to early startups with innovative drugs. They also help free up manufacturing capital in large pharmaceutical companies so they can invest in new pipelines."*
>
> — Joyce Lifland, Senior Sales Executive, Apprentice

When emerging biotech companies want to make a new product, they send their batch record to a CDMO for review. From there, the CDMO will interpret the record to determine if they're able to manufacture the product. They will then update the record to reflect how they can manufacture the product.

If it is possible, they can begin production soon thereafter. If it isn't, the biotech company can continue to look for another CDMO that is equipped with the right people, technology, and equipment to produce the product.

So why are they on the rise right now? CDMOs are uniquely prepared to handle the growing push for CGT therapies. As the demand for CGT rises, organizations need to refocus their efforts on making smaller batches for select groups of customers. In this case, organizations ask: "How can we scale this production process?"

To solve this problem, organizations are turning to CDMOs and this trend is evident by the growing market size. In 2021, the pharma CDMO market was valued at $186.62 billion. By 2027, it's expected to reach $289.64 billion, representing a CAGR of 7.29%.

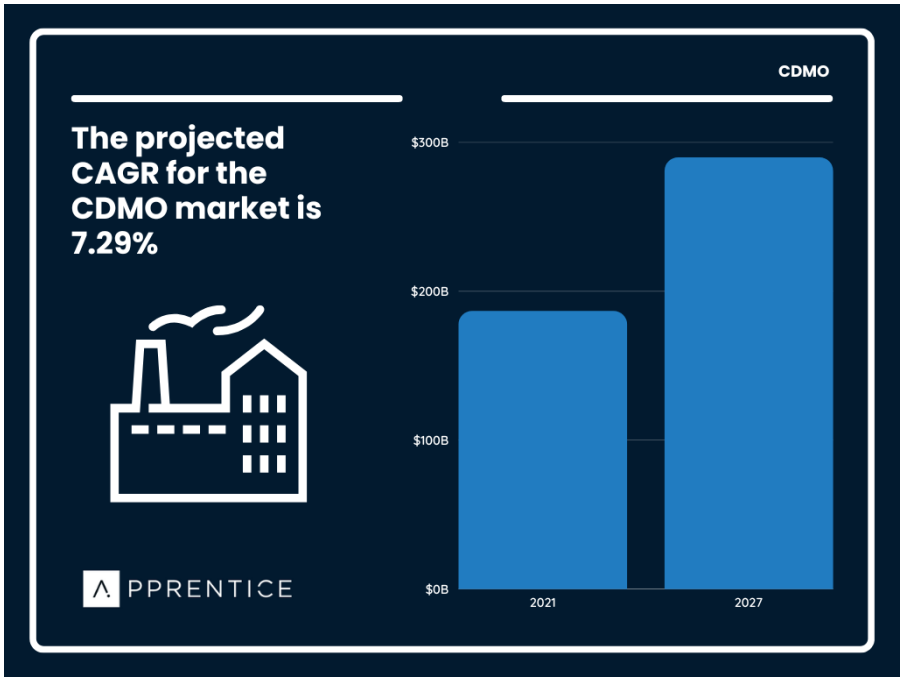

Figure 3: Projected CAGR of 7.29% for CDMOs from 2021 to 2027 [Source: BioPharma]

The bottom line? In-house production is becoming less common, as more companies opt to fully outsource manufacturing.

Emerging biopharma companies are responsible for 65% of the molecules in the R&D pipeline. [Source: IQVIA]

TREND #8

Move Towards Precision Medicine

In the past, doctors prescribed treatment options based on the disease category patients fall under.

Although effective for some people, for others this approach may result in unintended side effects. To reduce risk and improve the quality of care, physicians and researchers have turned their attention to more targeted mechanisms.

This new approach analyzes the individual patients' DNA, health status, and family history to understand what types of therapeutics would work best. From there, clinicians can take a strategic approach and treat diseases in a precise, highly targeted manner.

Although generally rolled up as "personalized medicine," there has been an increasing shift towards the term "precision medicine" for how the medical community is thinking and talking about this approach. While these two terms can be sometimes used interchangeably, there is a clear difference in what they mean and even moreso, what they imply:

Personalized medicine connotes an approach that's tailored to a specific individual patient; their resources, their preferences, and their demographics such as age and gender.

In contrast, **precision medicine** refers to a focus on one specific element of that individual patient: their genetic makeup. This targets the most data-informed and the most replicable element of an individual's background, without accounting for all of the added layers of complexity of an individual's unique response and clinical history.

> *"Personalized medicine focuses on adjusting treatment to individual differences rather than the genetic polymorphisms of lesser importance. With precision medicine, in the ideal sense, this personalized approach is merely taken up a notch by using genomic data to determine which type of drug protocol will serve the patient best, depending on the individual's metabolism."*
>
> — Dr. Liji Thomas, MD

In precision medicine, individual patients are categorized into subgroups based on their genetic makeup and susceptibility to different diseases. This not only lowers the burden for practicing physicians, it **improves diagnostic accuracy** and paves the way for a more streamlined, data-informed approach to targeted medicine.

In conjunction, precision medicine can also paint a future outlook on which people are susceptible to specific diseases, based on variations in genes, RNA, and proteins. The hope is that this information will allow clinicians to proactively treat people before issues arise.

Pharma companies can take precision medicine to the next level by leveraging AI-powered technologies, such as cloud-based **manufacturing execution systems**. These cutting-edge solutions can be customized to allow for patient-specific batch release criteria, which makes personalized medicine a viable option.

Since 2022, precision medicines have comprised ~35% of all FDA-approved therapeutic molecular entities in four of the last five years. [Source: Grand View Research]

TREND #9

Shifting Market Conditions

It's no secret that the economy is spiraling downward, while costs continue to rise.

From supply chain volatility to rising competition, increasing litigation costs, and changing consumers preferences, many pharma companies are struggling to keep up.

In addition, patent cliffs threaten many organizations' blockbuster drugs — with seasoned and emerging players waiting on the sidelines for an opportunity to release generic or biosimilar alternatives.

Furthermore, workforce expectations have been shifting as a result of the COVID pandemic. For example, many employees now expect flexible, hybrid, or remote work options.

To accommodate the workforce, pharma companies are under increasing pressure to go digital and adopt cloud-based solutions that enable teams to collaborate from anywhere, at any time.

There are also pending questions about when the "next" pandemic will emerge, and if we'll be prepared. This puts increasing pressure on organizations to innovate faster and more efficiently than ever before.

Then there's the rise of AI-powered technologies and machine learning, which streamlines the flow of information and enables new players to emerge on the scene and gain market share.

To navigate these uncertainties, adopting cutting-edge technology that accelerates production from start to finish isn't just an option — it's a must.

In 2019, the average cost of a pharma patent case increased by 67%, to $2.5 million. [Source: Bloomberg Law]

TREND #10

Rise of Blockchain Technology

Nowadays, blockchain technology applications are popping up in virtually every industry, including automotive, government, insurance, consumer goods, and telecommunications.

While this technology is typically used to secure personal information and make financial transactions, it's also trickling into the pharma industry.

In late August of 2022, Pfizer adopted blockchain technology. The pharma giant invested $500,000 in **VitaDAO**, a "community owned collective" that funds early stage research for longevity therapeutics. This move is pivotal for the industry, as other large and emerging pharma companies are likely to follow suit.

If you're confused about what makes the blockchain so appealing to pharma companies, you aren't alone. Like any disruptive technology (remember the internet of the 90's?), it's currently a gray area.

Pharma companies are trying to get to the heart of the puzzle with questions such as "What are the specific use cases?" and "How practical is this technology?"

Although the jury is still out about how this technology will impact pharma in the long term, there are several obvious benefits it can provide. These include:

- A highly secure, decentralized network to handle sensitive data
- The ability to trace the origin of pharmaceutical, the transport of drugs, and the procurement of raw materials
- A reduced need for intermediaries to be involved in pharma process
- Reduced costs and improved safety throughout every stage of pharmaceutical manufacturing

As the technology continues to work out its kinks, and move from the "Wild West" into a stabilized model for businesses, pharma organizations will continue to hop aboard and find new practical use cases to streamline their manufacturing operations.

The blockchain healthcare market is worth $7308.32 million, and is projected to grow at a 76.30% CAGR by 2028. [Source: Verified Market Research]

Closing Thoughts

As this trend report outlines, the pharma industry is poised for massive growth and disruption in 2023.

Given market volatility and economic uncertainty, it's more important now than ever for pharma companies to embrace new technologies, especially cloud-based solutions, that will enable them to reduce costs, increase safety, and speed up time to market.

Meet Keith: Our Featured Expert

When it comes to pharmaceutical manufacturing, Keith Bowen might as well have a crystal ball. His insights in the pharma space are spot on, and he's got a lot of visions for the year ahead! Read on to meet Keith and learn his top recommendation for 2023.

Who: Keith Bowen
What: LES and MES Advocate, Apprentice
When: 10 months at Apprentice
Where: Dublin City, Ireland
Why: Keith's industry knowledge and passion for sharing it is legendary!

Keith's Background

With 24 years of experience in the life science industry, Keith is well respected for his knowledge of and experience with MES product development, solution design, system integration, implementations, and support services for both large and small MES projects.

Keith has worked with many of the Top 10 Pharma, Biotech and Medical Device companies, on both automation and MES solutions. Today, he is an MES/LES Advocate at Apprentice and works primarily with new customer engagement, interfacing between sales, product, and marketing.

Keith's Top Take for 2023

> *"My top recommendation for organizations looking to achieve success in 2023 and beyond is to think about data flow for both internal and external manufacturing collaboration such as documents, operations, schedules, master data, inventory and/or equipment as inputs and outputs for your business.*
>
> *The future is all about the data. Not just being able to collect and move it electronically in a push button way to increase speed and maximize supply, but to leverage the data to make decisions at every level of an organization from the shop floor to C-level executives across the product life cycle and portfolio."*
>
> — Keith Bowen, MES/LES Advocate, Apprentice

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Meet Our Pharma Problem Solvers

Got questions? We're here to help! Reach out to our team of experts to talk about your needs and discuss how our platform can assist you. From preclinical benchtop to large-scale commercial manufacturing, we keep your global teams connected, empowered, and in sync.

[Get in Touch with Us >]

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We're Apprentice, your partner in making medicine.

Despite incredible therapeutic innovations, the process for manufacturing these life-changing drugs is stuck in the past. Legacy paper-based systems can't hold up to the demands of new therapies or the pressures of new production methods.

Enter Apprentice. We're your trusted partner to bring your operations up to speed with the transformative power of AR tech. Our mission is to simplify your process.

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